K012957

Appendix A (Summary of Safety And Effectiveness)

MAR 6 2002

Submitter:
John Gagliardi, President **(contact person)**
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Maineville, OH 45039
513-573-0085 (Telephone and fax) **or**
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Trade Name: Towel Drape

Common Name: Towel Drape

Classification Name: Surgical Towel Drape

Summary of Safety and Effectiveness:

The Dynarex Towel Drape is substantially equivalent in function and intended use to the DEKA Medical Surgical Drape – K980210, Invotec International Drape – K911039 and the 18" x 26" Towel Drape, manufactured **for** Dynarex Corporation (see example of labeling in Appendix D). These products are presently on the market.

Specifically:
the Dynarex Towel Drape is exactly similar in functional design, performs the same functions and has the same intended use as these presently distributed devices. The packaging methods and packaging materials are exactly the same, respectively.

The Dynarex Towel Drape is composed of nonwoven fabric or polyethylene film and are of various configurations appropriate for General Surgical Procedures. These devices use non-woven and film materials as a protective patient covering during surgical procedures. These barrier materials are essentially impervious to fluid transfer across them, thus function to isolate the operative site from the surrounding area. Dynarex Towel Drapes may feature tape adhesive to temporarily bind the drape to the periphery of the operative site. Fluid collection pouches are attached to the drape for collection of operative wound solid and liquid effluents. The Dynarex Towel Drape will be subjected to a sterilizing dose of gamma radiation sufficient to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

This towel drape is a single use, disposable product provided in a sterile package. The method of sterilization and the method used to validate the sterilization process are in compliance with ANSI/AAMI/ISO 11137:1994, Sterilization of Health Care Products----- Requirements for Validation and Routine Control-----Radiation Sterilization. The sterility assurance level (SAL) intended for the Dynarex Towel Drape is 10^{-6}. This is assured through product dosimetric release that is achieved with each lot of sterilized product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 6 2002

Dynarex Corporation
C/O John Gagliardi
Midwest Process Innovation
7736 Woodside Court
Mainsville, Ohio 45039

Re: K012957
Trade/Device Name: Dynarex Towel Drape
Regulation Number: 878.4370
Regulation Name: Towel Drape
Regulatory Class: II
Product Code: KKX
Dated: January 28, 2002
Received: January 31, 2002

Dear Mr. Gagliardi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Dynarex Towel Drape
K012957

Indications for Use: The Dynarex Towel Drape is a device consisting of natural or synthetic materials intended to be used as a patient covering during General Surgical Procedures.

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012957